

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|---------------------------|---|----------------------------|
| In re Application of:     | ) | Art Unit: 1639             |
|                           | ) |                            |
| ST. HILAIRE, et al.       | ) | Examiner: WESSENDORF, T.   |
|                           | ) |                            |
| Serial No.: 10/541,501    | ) | Washington, D.C.           |
|                           | ) |                            |
| Filed: July 7, 2005       | ) | August 7, 2008             |
|                           | ) |                            |
| For: AFFINITY FISHING FOR | ) | Docket No.: ST. HILAIRE=1A |
| LIGANDS AND PROTEINS      | ) |                            |
| RECEPTORS                 | ) | Confirmation No.: 4075     |

PETITION TO VACATE ERRONEOUS HOLDING OF NON-RESPONSIVENESS

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S i r :

On November 7, 2007, the PTO mailed its first action on the merits. Applicants filed an amendment, in response to that action, on March 6, 2008 (with Petition and fee for a one-month extension of time).

On June 11, 2008, the PTO mailed a notice holding that the March 6, 2008 amendment was not fully responsive under 37 CFR 1.135(c) because:

- (1) the amendments to claim 43 introduce new subject matter not corresponding with the indicated allowable subject matter (HY6);
- (2) the new claims introduce subject matter which have not been considered and examined before;
- (3) the continued use of the tables in claims 43 and 90, which we defended as justified by "exceptional circumstances" per MPEP 2173.05(s), is allegedly improper; and
- (4) we allegedly failed to pay fees for the new claims.

Applicants respectfully urge that points (1)-(3) are not a proper basis for a holding of non-responsiveness, and, as to point (4), that in fact all fees were paid.

The test for whether an amendment is fully responsive to a nonfinal action is whether it (1) substantially responds to each rejection, objection and requirement, and (2) is a bona fide attempt to advance the case to final action. See MPEP 714.03. The applicant need not adopt the examiner's suggestion for amending the claims to overcome a particular rejection or objection; the applicant may instead contend that the rejection or objection is wrong as a matter of law or inappropriate in view of the particular facts. The applicant may add claims, or amend claims, even if that might raise new issues, so long as the applicant has responded, at least by argument, to all outstanding issues.

Hence, the holding of non-responsiveness should be vacated and the case returned to the examiner for the preparation of a new action on the merits.

With regard to point (1), the amendment to claim 43 was actually a narrowing amendment, as the now-eliminated dependency on 88 didn't structurally limit the ligand, and we limited the allowed amino acids to those of tables 1, 2, 3, 7 and 9.

Moreover, even if claim 43 had been amended to include previously unclaimed subject matter, such an amendment is allowed as of right, provided that there has been no final rejection or Ex parte Quayle action. Cp. MPEP 714.19(A) and 714.20(C). The Examiner can limit examination of the amended claim to the elected species, but can't refuse to enter the amendment. Amendments in a nonfinal case, which comply with formalities (cp. 37 CFR 1.121), are entered as a matter of right. See MPEP 714(I) (A).

With regard to point (2), we added claims to a method of binding a protein. While such claims were not previously presented, we reiterate that when a case is nonfinal, applicants are permitted to add claims, even claims directed to previously unclaimed categories of invention. If such claims are directed to independent or distinct inventions, then it may be appropriate for such claims to be held withdrawn under the doctrine of

constructive election. See MPEP 821.03.

However, it should be noted that the new claims are directed to a method of using the ligand of claim 43, and that MPEP 821.04(a) specifically allows dependent process claims (or equivalent) if the base product claim is allowable. Given the Examiner's admission that HY6 is allowable, it seems likely that at least claim 99 would be rejoinable under MPEP 821.04(a).

MPEP 821.03 further implies that a holding of non-responsiveness is not the proper action for the Examiner to take when new claims, drawn to a "new" invention, are added after first action on the merits.

With regard to point (3), we appreciate that the Examiner disagrees with us that the table reference is justified by "exceptional circumstances". We are entitled to make the argument, the examiner is entitled to disagree and to maintain the rejection of claim 90 and extend it to claim 43, and we can then either concede the point and replace the table reference with an explicit litany of amino acids, or appeal the indefiniteness rejection. What the examiner is not entitled to do is to hold that our defense of the use of tables is non-responsive and deny us the opportunity to ultimately put the definiteness issue before the Board.

The final issue is the matter of payment of fees. According to the cover sheet of the amendment, 2 independent and 16 total claims remained in the case after amendment. That is correct. We are entitled to up to 3 independent and 20 total claims for the basic filing fee. We in fact originally paid (July 12, 2006) for 22 total claims. And if, somehow, we had failed to pay for a new increase in the number of claims, our cover sheet includes a blanket deposit account authorization for presentation of extra claims under 37 CFR 1.16. Thus, we have manifestly satisfied MPEP 710.04 (pay for new claim before it is considered by the Examiner).

We note for the sake of completeness that on even date herewith we filed a supplemental amendment which eliminated

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references to the tables from claims 43 and 90, thereby mooting point (3). However, we would nonetheless like it clearly established that point (3) was not a proper basis for a holding of non-responsiveness, since it is still relevant to whether any patent term adjustment is reduced pursuant to 37 CFR 1.704(c)(7). Since the deletion of the tables in a supplemental response was expressly requested by the examiner, there should be no reduction pursuant to 37 CFR 1.704(c)(8).

Respectfully submitted,

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